Iowa Department of Public Health
Bureau of Radiological Health

Mammography Facility Application

Facility Information

Facility Name
MQSA Facility ID
Employer/Tax Identification number
Has this facility been previously accredited? No

If YES, enter previous accreditation information
MQSA ID
MQSA Expiration Date

Physical Address
City, State, ZIP
Facility Phone #
Facility Fax #

Total number of mammography units:

Total number of Radiologist Review Workstations used by this facility:
(onsite and offsite)

Total number of printers used by this facility:
(onsite and offsite)

Total number of mammography procedures performed annually at this facility:

Applying with IDPH for*: Choose One

*Choose accreditation if your facility accredits with the Iowa Department of Public Health
*Choose authorization if your facility accredits with the American College of Radiology

DO NOT COMPLETE THIS SECTION UNLESS DIRECTED TO BY IDPH
ADDITIONAL SITE associated with this facility – IF APPLICABLE

Site Name
Physical Address
City, State, ZIP
Site Telephone #
Site Fax #

Mammography Facility Application

Facility Contact Information

CEO/Hospital Administrator

Name
Title
Telephone
Email Address

Inspection Contact - person to contact to schedule inspections

Name
Title
Telephone
Email Address

Accreditation Contact *(if different than Inspection Contact)* - person who will receive accreditation paperwork from IDPH

Name
Title
Telephone
Email Address

Lead Interpreting Physician

Name
Address
City, State, ZIP
Telephone
Email Address

Billing Contact - person who will receive the bill

Name
Title
Address
City, State, ZIP
Telephone
Email Address

Mammography Unit Information

(complete separate page for each unit - additional pages found at end of this document)

Mammography Unit Room Name
Mammography Unit Manufacturer* Select One
Mammography Unit Model* Select One
Serial Number
Manufacture Date

Mammography Mode Select One
CR System Mfg. (if applicable): Select One

Unit to be used for Tomosynthesis? No
If YES, FDA approval needed prior to using tomosynthesis mode on patients.

Unit in a mobile truck? No
Mobile truck used at sites other than primary location? No
If YES, complete additional sites form with this application. (Page 6)

Unit located at additional site? No
If YES, prior IDPH approval is needed

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*If you do not see your mammography unit manufacturer or model listed, you must contact the mammography program staff.

Radiologist Review Workstation Information

Complete separate form for each RWS - additional forms found at end of this form

An RWS consists of one workstation software driving 2 to 4 monitors approved by the FDA for mammography interpretations.

RWS Room Name		
RWS Software	Select One	

(this could be provided by either RWS or PACS vendor)

RWS Location – Address, City, State, ZIP

RWS Monitor 1 Manufacturer	Select One	
RWS Monitor 1 Model		
RWS Monitor 1 Serial Number		
RWS Monitor 1 Manufacture Date		

RWS Monitor 2 Manufacturer	Select One	
RWS Monitor 2 Model		
RWS Monitor 2 Serial Number		
RWS Monitor 2 Manufacture Date		

Information on 3rd and 4th monitors for RWS configurations of more than 2 monitors

DO NOT COMPLETE UNLESS RWS HAS MORE THAN 2 MONITORS

RWS Monitor 3 Manufacturer	Select One	
RWS Monitor 3 Model		
RWS Monitor 3 Serial Number		
RWS Monitor 3 Manufacture Date		

RWS Monitor 4 Manufacturer	Select One	
RWS Monitor 4 Model		
RWS Monitor 4 Serial Number		
RWS Monitor 4 Manufacture Date		

Printer Information

Complete separate form for each printer

Printer Room Name

Printer Location – Address, City , State, ZIP

Printer Manufacturer	
Printer Model	
Printer Serial Number	
Printer Manufacture Date	

Mobile Sites

Use additional pages as needed

Site Name	
Address, City, State, ZIP	
Typical schedule	
(i.e. M-F, M and Th, monthly)	

Site Name	
Address, City, State, ZIP	
Typical schedule	
(i.e. M-F, M and Th, monthly)	

Site Name	
Address, City, State, ZIP	
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Address, City, State, ZIP	
Typical schedule	
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Personnel Information

Personnel Information – Interpreting Physicians

Personnel Information - Mammography Technologists

Quality Control Technologist

(Single person named to oversee QC - must be qualified mammography technologist)

Mammography Technologists

Personnel Information - Medical Physicists

Be sure to list physicists providing surveys for all components in use by your facility.
Off-site components may have a different physicist than your facility.

Signature Page

The Lead Radiologist and Administrator/CEO must sign this document. By signing this document, you are providing assurance that this facility will meet all provisions of the rules outlined in Iowa Administrative Code Chapters 38 through 41 applicable to mammography and regulations outlined in the Federal Register (CFR) 900.12 Mammography Quality Standards Act (MQSA).

1. **Each radiation machine and ancillary component is specifically designed and configured for mammography use.**
2. **The mammography unit meets the applicable equipment requirements described in the FDA's Mammography Quality Mammography Standards Act and the Iowa Administrative Code (IAC) Chapters 38-41.**
3. **Your facility will notify the Iowa Department of Public Health in writing regarding changes to this application. IDPH notification is required prior to making any changes to mammography unit, radiologist review workstation, or printer. All other changes must be reported within 30 days of any changes to the information this application.**
4. **Lead Interpreting physician signature serves as attestation that all personnel meet the requirements of CFR 900.12(a) "Mammography Quality Standards Final Rule" that became effective on April 28, 1999 and IAC Chapter 41.6.**
    - **New facilities must submit supporting documentation with this application.**
    - **Supporting documentation for existing facilities will be checked during the annual MQSA inspection.**
5. **Lead Radiologist has reviewed the procedure manuals and deems them appropriate in order to meet all applicable regulations and requirements.**
6. **To the best of my (signatory) knowledge and my belief, the information provided in this document is true and correct. I understand that the State of Iowa or FDA may request additional information to substantiate the statements made in the document. I understand that knowingly providing false information in a matter within the jurisdiction of an agency of the United States could result in criminal liability, punishable by up to $10,000 fine and imprisonment of up to five years, or civil liability under MQSA, or both.**

Signature Lead Interpreting Physician	Date
Signature Administrator/CEO	Date

Iowa Department of Public Health
Bureau of Radiological Health

Additional Page - Complete ONLY if needed!!

Mammography Facility Application

Mammography Unit Information

(complete separate page for each unit - additional pages found at end of this document)

Mammography Unit Room Name	
Mammography Unit Manufacturer*	Select One
Mammography Unit Model*	Select One
Serial Number	
Manufacture Date	

Mammography Mode	Select One
CR System Mfg. (if applicable):	Select One

Unit to be used for Tomosynthesis? No

If YES, FDA approval needed prior to using tomosynthesis mode on patients.

Unit in a mobile truck? No

Mobile truck used at sites other than primary location? No

If YES, complete additional sites form with this application. (Page 6)

Unit located at additional site? No

If YES, prior IDPH approval is needed

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*If you do not see your mammography unit manufacturer or model listed, you must contact the mammography program staff.

Mammography Unit Information

(complete separate page for each unit - additional pages found at end of this document)

Mammography Unit Room Name	
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Serial Number	
Manufacture Date	

Mammography Mode	Select One
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Radiologist Review Workstation Information

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RWS Room Name
RWS Software — Select One
(this could be provided by either RWS or PACS vendor)

RWS Location – Address, City, State, ZIP

RWS Monitor 1 Manufacturer	Select One	
RWS Monitor 1 Model		
RWS Monitor 1 Serial Number		
RWS Monitor 1 Manufacture Date		
RWS Monitor 2 Manufacturer	Select One	
RWS Monitor 2 Model		
RWS Monitor 2 Serial Number		
RWS Monitor 2 Manufacture Date		

Information on 3rd and 4th monitors for RWS configurations of more than 2 monitors

DO NOT COMPLETE UNLESS RWS HAS MORE THAN 2 MONITORS

RWS Monitor 3 Manufacturer	Select One	
RWS Monitor 3 Model		
RWS Monitor 3 Serial Number		
RWS Monitor 3 Manufacture Date		
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RWS Monitor 2 Model	
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RWS Monitor 3 Manufacture Date	

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RWS Monitor 2 Model		
RWS Monitor 2 Serial Number		
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RWS Monitor 3 Model		
RWS Monitor 3 Serial Number		
RWS Monitor 3 Manufacture Date		
RWS Monitor 4 Manufacturer	Select One	
RWS Monitor 4 Model		
RWS Monitor 4 Serial Number		
RWS Monitor 4 Manufacture Date		

Printer Information

Complete separate form for each printer

Printer Room Name

Printer Location – Address, City , State, ZIP

Printer Manufacturer	
Printer Model	
Printer Serial Number	
Printer Manufacture Date	

Mobile Sites

Use additional pages as needed

Site Name	
Address, City, State, ZIP	
Typical schedule	
(i.e. M-F, M and Th, monthly)	

Site Name	
Address, City, State, ZIP	
Typical schedule	
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